



Hackensack
Meridian *Health*

RESEARCH ROUNDUP

SUMMER 2023



HMH RESEARCH NEWS



MESSAGE FROM THE **PRESIDENT OF ACADEMICS, RESEARCH, AND INNOVATION**

The Hackensack Meridian Health Research Institute continues to bring together an ecosystem of research, education and expertise across the state's largest health network. This is perhaps best seen in our Annual Symposium - and also in our inclusion among Fortune's Most Innovative Companies list. We are doing great things.

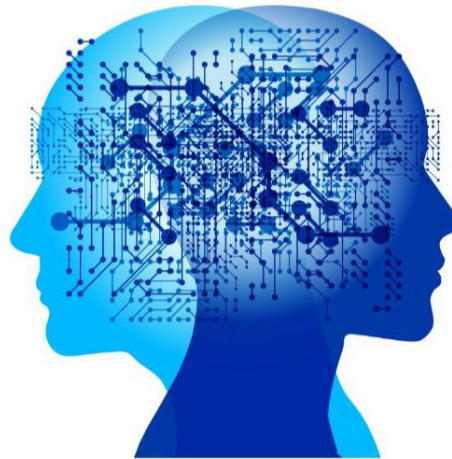
Ihor Sawczuk, M.D., FACS



NOTE FROM THE **VICE PRESIDENT**

It is exciting to watch the entire network's talent and experience make progress in so many different ways. Grants keep coming in, because our team members are proving they are at the cutting-edge in so many ways.

Cheryl Fittizzi, RN, MBA, CIP,
Vice President of Research and
Regulatory Affairs



Research Symposium Highlights Extraordinary HMH Research

The Annual HMHRI Research Symposium, which took place on June 1, 2023, featured some of the most promising research throughout the Hackensack Meridian Health network.

The event commenced with opening remarks from the network's research leaders including:

Ihor Sawczuk, M.D., FACS, the president of Academics, Research and Innovation for the network; Jeffrey Boscamp, M.D., president and dean of the Hackensack Meridian School of Medicine (HMSOM); and David Perlin, Ph.D., chief scientific officer and executive vice president of the Center for Discovery and Innovation (CDI).

The speakers following them came from different departments from across the network, including the CDI, Heart and Vascular, Pediatrics, Digital Technology Services, Surgery, Neurosurgery, Psychiatry and Nursing. The nature of their lectures also ranged from the highly technical - including presentations on the research data platform at HMH and on creating research databases - to the more clinically focused, including presentations on Alzheimer's disease, Parkinson's disease and sickle-cell anemia. Some other highlights were presentations on cancer, bacterial transmission and the role of neuroplasticity in neuropsychiatric patients.

The final presenters were awardees from the Resident/Fellow Research Day and the Medical School Research Day who delivered their winning presentations. Stanley Terlecky, Ph.D., vice dean of Research and Medical Sciences at HMSOM, capped the day with closing remarks.

The full day event drew more than 140 attendees who engaged with the presenters by asking questions and offering feedback about their presented work. Attendees' interest even prompted more specific follow-up events in the near future, including the upcoming presentation of Mr. Sameer Sethi, SVP, chief data and analytics officer, on research databases for the Investigator Training Lecture Series.

KEEP GETTING BETTER



Hackensack
Meridian Health



Hackensack Meridian Health Invests in Canary Speech, Company with AI Software to Assess Anxiety, Wellness in Spoken Words

HMH and Bear's Den Invest in Company to Detect Mental and Cognitive Health Problems Hinted in Speech Patterns

Hackensack Meridian Health and its Bear's Den innovation accelerator program are making a strategic investment in Canary Speech, a company that uncovers valuable insights into disease and well-being encoded in human speech.

Canary's patented technology monitors a variety of health factors in a fast, non-invasive, and accurate way: by assessing "digital biomarkers" in the human voice to explain or predict energy levels and health-related outcomes. The technology tracks the presence and severity of a variety of targeted diseases, such as anxiety, depression and cognitive decline. The resulting vocal scores can replace subjective measurements with objective, actionable care solutions.

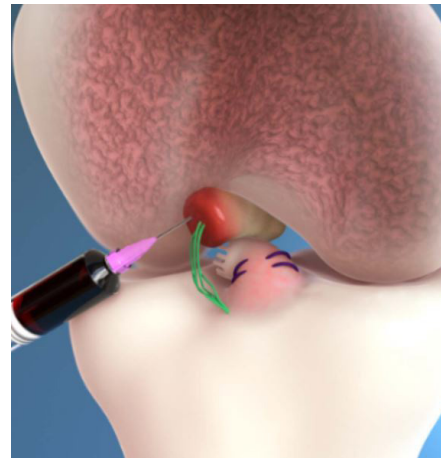
"This is a fascinating innovation, and we're eager to support a promising way to leverage technology for wellness," said Robert C. Garrett, FACHE, chief executive officer of Hackensack Meridian Health. "Artificial intelligence is impacting every aspect of modern life, and our health network wants to help accelerate the efforts of companies like Canary Speech."

"We are thrilled to partner with Hackensack Meridian Health, and welcome their support," said Henry O'Connell, Canary Speech chief executive officer and co-founder.

Canary Speech's patented speech analysis technology provides clinical-grade screening for mood states and disease using proprietary machine-learning modeling.

The human voice inherently reveals both emotional and physiological states. Canary's technology unlocks voice as a vital sign unto itself, modeling both acoustic and linguistic features to measure stress, mood and energy within the patterns, inflections and timing of those words.

Developed by the neurology and speech AI team behind Amazon Alexa, Canary Speech powers first-of-its-kind insight into the full applications of vocal biomarkers in healthcare. [READ MORE](#)



HUMC Performs Innovative BEAR Procedure in New Jersey for ACL Reconstruction

Orthopedic surgeons at Hackensack University Medical Center performed the Bridge Enhanced

ACL Restoration (**BEAR**) Implant operation to reconstruct the injured knee ligament of a 15-year-old soccer player. The BEAR Implant is an innovative treatment that promotes the body's own healing processes to join the ends of a torn anterior cruciate ligament (ACL), one of the most common sports injuries.

"The BEAR Implant is the first device developed to help a person's ACL heal on its own," explained Hackensack University Medical Center orthopedic surgeon Amit Merchant, M.D., who performed this procedure as well as a second BEAR operation with orthopedic surgeon Yair David Kissin, M.D. "This approach offers an alternative to conventional ACL reconstruction which uses a tendon from another part of the patient's body. That can leave a patient with pain where the tendon was retrieved." Such "autografts" are usually tissue taken from the patellar tendon, quadriceps tendon or hamstring.

The patient, Kelis Guzman, is a 10th-grader from Hasbrouck Heights, New Jersey, who plays on the New Jersey Crush Girl Academy-level soccer team as well as in the Elite Clubs National League (ECNL) — a more intense level of play. At an exhibition game in February, after executing a side tackle, she felt her left knee pop and click when she stood up. "It wasn't painful, but it felt very unstable," she recalled. "Something was definitely wrong." She sat out the rest of the game, believing it might be a muscle sprain.

A visit to a local emergency room showed nothing suspicious on an x-ray, so the doctor sent her home. After a few days, it hurt to flex her leg and she had limited range of motion. Her mother, Karin — a Patient Access Specialist at Hackensack University Medical Center — took her to see Dr. Merchant, who had treated Kelis in 2021 for a broken ankle. An MRI confirmed she had torn her ACL. [READ MORE](#)

Hackensack Meridian Neuroscience Institute at JFKUMC Awarded Grant to Study Repair to Central Nervous System Damage from Chronic Alcohol Abuse

Hackensack Meridian Neuroscience Institute at JFK University Medical Center announced today that it has been awarded a major research grant from the National Institute on Alcohol Abuse and Alcoholism, part of the U.S. National Institutes of Health (NIH), to study a novel approach to treat damage to the central nervous system from chronic alcohol abuse. The two-year award of \$464,887 is part of the highly competitive NIH grant application process that recognizes innovative scientific projects. NIH-funded research has led to scientific breakthroughs and new treatments that help people live longer, healthier lives.

The NIH grant will fund a project entitled “Peptide therapy for alcohol-induced central nervous system injury,” proposed by Mohammed Abdul Muneer, MSc, Ph.D., research scientist and principal investigator, Hackensack Meridian Neuroscience Institute at JFK University Medical Center, and associate professor of Neurology at the Hackensack Meridian School of Medicine.

Their work hypothesizes that the neuroinflammation, neurodegeneration and cognitive deficits that result from alcohol-induced oxidative damage to neurons in the brain can be repaired by activating the antioxidant signaling Nrf2 (nuclear factor E2-related factor 2) pathway using a small Nrf2 activator III peptide, referred to as Nrf2 peptide.

“We at the Hackensack Meridian Neuroscience Institute at JFK University Medical Center are both honored and humbled to be awarded this NIH grant,” said Gregory J. Przybylski, M.D., MBA, chairman, Neuroscience Institute at JFK University Medical Center, and professor of Neurosurgery at the Hackensack Meridian School of Medicine. “Our neuroscientists are working to unravel the complex mechanisms of the diseases of the brain and central nervous system. This project is a great example of how our innovation has the potential to deliver possible new approaches to treat brain diseases. Congratulations to Dr. Muneer for this remarkable achievement.” [READ MORE](#)

HUMC Investigators Present Pioneering Research at Annual Pediatric Cancer Meeting

Researchers from Hackensack Meridian Children’s Health at Joseph M. Sanzari Children’s Hospital at Hackensack University Medical Center presented seven studies at the American Society of Pediatric Hematology/Oncology (ASPHO) Conference in Fort Worth, Texas, in May. The nationally recognized hospital is home to the only pediatric stem cell transplant program in New Jersey and is one of the few treatment centers in the nation providing CAR T-cell immunotherapy for children and adolescents.

“Our doctors are consistently finding better ways to treat even the rarest types of cancer and challenging blood disorders in children,” said Alfred P. Gillio, M.D., chief of Pediatric Hematology at Joseph M. Sanzari Children’s Hospital. “We offer patients access to more than 100 national and international clinical trials. Some of the treatment protocols we use have been developed at our facilities and are only available at our children’s hospitals.”

“Each patient we treat benefits from a team of pediatric oncologists, surgeons, nurses, and other providers who specialize in children’s cancer care and work together as specialized treatment teams,” added Burton Appel, M.D., associate chief of Pediatric Hematology-Oncology. “These teams focus on each child’s specific diagnosis and promote strong relationships between patients, families and clinicians to deliver the most effective care.”

More than 1,200 pediatric hematology/oncology professionals from around the world attend the [ASPHO Conference](#) each year. The leading meeting for the field, the ASPHO Conference allows attendees to receive high-quality educational content, network with their colleagues and discover innovative advancements in pediatric hematology/oncology. [READ MORE](#)

HMH Ranked #1 in the U.S. on the 2023 DiversityInc Top Hospitals and Health Systems List

Hackensack Meridian *Health*, New Jersey’s largest and most comprehensive health care network, is proud to announce that it is ranked No. 1 in the nation on the 2023 [DiversityInc Top Hospitals and Health Systems list](#), a prestigious honor that recognizes the network’s expansive efforts to create a more diverse, equitable and inclusive workforce and to address disparities in health outcomes.

“Hackensack Meridian *Health* is deeply committed to advancing diversity, equity and inclusion across our network and ensuring that all communities have access to high-quality innovative healthcare,” said **Robert C. Garrett, FACHE, CEO of Hackensack Meridian Health**. “It’s an incredible honor to be recognized for these priorities and strategies that are having a real impact on our organization and in the communities we serve.”

Since 2001, the survey has been the most comprehensive, empirically data-driven D&I analysis based on organization-submitted information from some of the largest U.S. employers. The assessment collects data across six key areas: Leadership Accountability, Human Capital Diversity Metrics, Talent Programs, Workplace Practices, Supplier Diversity and Philanthropy.

“This is an absolute honor and Hackensack Meridian *Health* will continue to build a culture that reflects the diversity of our great state and ensures that everyone has a chance to thrive,” said **Avonia Richardson-Miller, EdD, MA, CDE, senior vice president and Chief Diversity Officer at Hackensack Meridian Health**. “We are equally committed to continuing to advance health equity in New Jersey and beyond.” [READ MORE](#)



Fungal Infections an Unintended Consequence of Advanced Immunotherapy, Research Shows

Major fungal infections have become more common across the globe, and one unexpected phenomenon among the rise of fungi is life-threatening infections as a result of a complication of certain immunotherapies and small molecule kinase inhibitors.

A scientist at the Hackensack Meridian Center for Discovery and Innovation (CDI) has identified the specific mechanistic cause of one such phenomenon, which will likely save lives into the future, via a new publication.

The paper, titled “C5a-licensed phagocytes drive sterilizing immunity during systemic fungal infection,” [appeared in the journal Cell on May 22.](#)

“Our findings will assist clinicians in their understanding of how these life-threatening infections are emerging,” said Jigar Desai, Ph.D., assistant member of the CDI, assistant professor of medical sciences at the Hackensack Meridian School of Medicine, and first author of the paper. “These findings may help doctors and scientists alike better understand how some of these cases arise - and how to avoid them.”

The team of scientists established that the C5a protein, the penultimate effector constituent of the complement pathway, is key to the body’s innate ability to fight systemic fungal infections. Additionally, the team also identified enhanced complement pathway signature acts as a predictive biomarker for systemic candidiasis. With the use of animal models, patient data and sera, the team showed how C5a and its downstream effects are crucial for the body’s immune cells, specifically neutrophils and macrophages, to clear the fungus *Candida albicans*, when it has overtaken the body’s natural defenses. [READ MORE](#)



CDI Lab Earns Grant to Re-Engineer Drugs to Combat Emerging Infections

A laboratory at the Hackensack Meridian Center for Discovery and Innovation (CDI) has been issued a major grant to repurpose drugs to combat non-tuberculous mycobacteria (NTM), an emerging family of germs naturally found in soil and water and which can be deadly to those with compromised immune systems and pre-existing lung diseases.

The \$2.6 million, five-year grant enables the laboratory of Thomas Dick, Ph.D., to re-engineer tuberculosis (TB) drugs to work against NTM like *Mycobacterium abscessus*, which are TB’s biological cousins.

The federal grant, from the National Institutes of Health -National Institute of Allergy and Infectious Diseases, focuses on strategically re-engineering rifabutin to overcome NTM resistance, according to Dr. Dick. It’s the fourth major grant for the scientist and his lab supporting NTM/TB research since he moved from the National University of Singapore to the United States in 2017. “The good news: things are happening. Compared to a couple of years ago we now have some compounds against NTM being evaluated,” said Dr. Dick, member of the Center for Discovery and Innovation and professor at the Hackensack Meridian School of Medicine. “However, it’s by far not enough. The pipeline is still very weak. We’re helping to strengthen the pipeline with attractive candidates.”

Rifabutin, first approved by the U.S. Food and Drug Administration in the 1990s for tuberculosis, is the focus of the Dick Lab’s work. That work so far indicates that rifabutin works more effectively than rifampicin against *M. abscessus* - and they have shown that rifabutin can be further tailored to overcome intrinsic resistance the bacteria have currently against the drugs available.

The new treatment pathway could provide drugs not just *M. abscessus*, but also other NTM germs. [READ MORE](#)

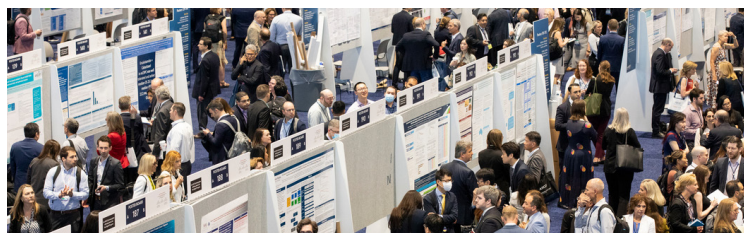
HMH Announces the Sheila Cancro Institute for Nursing Leadership and Practice Excellence

Hackensack Meridian *Health* is pleased to announce the creation of the Sheila Cancro Institute for Nursing Leadership and Practice Excellence to provide infrastructure, support and advocacy for nurses as they advance their careers, education and research. In addition, a New Career Initiative will help build a pipeline of new nurses by offering financial relief to students.

“One of the greatest challenges in healthcare in the U.S. today is attracting and retaining nursing talent,” said Robert C. Garrett, FACHE, chief executive officer, Hackensack Meridian *Health*. “In this fiercely competitive market, I am thrilled that we are able to advance new initiatives to support the professional growth of our nurses and ensure we are able to meet workforce demands now and in the future.”

The Institute is named after Sheila Cancro, a former nurse’s aide who instilled in her children the value of hard work, an entrepreneurial spirit and a heartfelt appreciation for caring for others. Her son Peter Cancro, the founder and CEO of Jersey Mike’s, a national sandwich franchise, made a generous donation to create the institute.

The Sheila Cancro Institute will provide a centralized structure that will offer new and enhanced pathways for Hackensack Meridian *Health* nurses to achieve professional and educational excellence. This includes the development of new programs, activities and resources that will increase leadership capacity, continuously promote higher-level skill sets and knowledge, facilitate structural empowerment and improve the health care experience for both patients and the nursing team. [READ MORE](#)

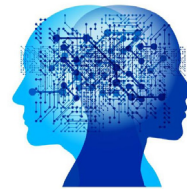


John Theurer Cancer Center Investigators Present Pioneering Research at Annual Cancer Meetings

Investigators from Hackensack Meridian John Theurer Cancer Center — part of the NCI-designated Lombardi Comprehensive Cancer Center at Georgetown University — and Hackensack University Medical Center presented data from 24 studies at the American Society of Clinical Oncology (ASCO) Annual Meeting, the largest gathering of cancer professionals. The meeting was held June 2-6, 2023, in Chicago.

Many of the studies focused on innovative therapies for blood cancers and novel immunotherapies. These are areas of expertise for John Theurer Cancer Center, one of the world’s leading centers for blood cancer treatment and home to one of the nation’s largest stem cell transplantation programs. The findings of these investigations have the potential to change the treatment and understanding of hematologic and other cancers. [READ MORE](#)

SOM Hosts Annual HUMC Neuroscience Meeting



The sixth annual Hackensack University Medical Center Neuroscience Symposium was held at the Hackensack Meridian School of Medicine on June 24, 2023.

The event featured key opinion leaders from Hackensack University Medical Center and the Hackensack Meridian School of Medicine, including neurologists, neurosurgeons, geriatricians, psychiatrists, physiatrists and others.

The point-counterpoint discussions focused on advancements and controversies in disorders including multiple sclerosis, Parkinson’s disease and essential tremor, stroke, brain tumor, epilepsy, dementia and neurocritical care.

A welcome was offered by Hackensack Meridian School of Medicine President and Dean Jeffrey Boscamp, M.D., and the emcee was Florian Thomas, M.D., associate dean of faculty, and founding chair and professor, Department of Neurology.

HMH Faculty Publish on the Role of the IRB (and Others) in Promoting Inclusion in Research

Increasing diversity and inclusion in research has been a hot topic lately. COVID-19 really brought this issue to the fore, but it had been a significant concern before the pandemic and continues to be a concern today. Yet whose responsibility is it to ensure that studies are well-represented, that vulnerable populations are included in research?

According to Dr. Bryan Pilkington, professor of Medical Sciences at the Hackensack Meridian School of Medicine (HMSOM), and Dr. Elli Gourni Paleoudis, director of the Investigator Initiated Research Program and Support Services at Hackensack Meridian *Health* and assistant professor of Medical Sciences at HMSOM, the responsibility should not lie with the Institutional Review Board (IRB) alone. The two recently published a commentary on this topic in the American Journal of Bioethics, where they argued that while the IRB is in a good position for decision making, the responsibility should be shared by other stakeholders as well.

“IRBs play an essential role in ensuring ethically and scientifically sound research, but the burden of inclusion should not be borne by them alone,” said Dr. Pilkington. “Understanding what IRBs do well, what their limitations are (especially around considerations of vulnerability), and what the rest of us can do is no small task but one that Dr. Gourni Paleoudis and I believe is a crucial step in continuing to research ethically.”

“Important stakeholders to be included in this discussion include, but are not limited to, the researchers themselves, funders and publishers from institutions such as the NIH, AMJ, and ICMJE,” added Dr. Gourni Paleoudis.

In the article, the authors specifically focus on the funders and editors, and demonstrate that those groups have significant means of promoting inclusion in research today. They provide (*cont’d*)

Role of the IRB (cont'd)

several examples of this, especially with respect to the fact that government funds incentivize the inclusion of different races and ethnicities and that [clinicaltrials.gov](https://www.clinicaltrials.gov) encourages transparency by requiring the reporting of race and ethnicity.

Drs. Pilkington's and Gouna Paleoudis's [article](#) is titled, "Don't Ask Too Much: Non-Maleficence as the Guiding Principle in IRB Decision-Making" and is available online. They are currently engaged in a research project assessing the understanding of vulnerability among IRB members and IRB staff.



Hackensack Meridian Health Named to Fortune Most Innovative List

We are brought into the future of health care by our forward-thinking, care-driven leaders and team members. It is their efforts that have been recognized by Fortune magazine, which has named Hackensack Meridian Health to their list of America's Most Innovative Companies.

This achievement celebrates the cutting-edge research of the **Hackensack Meridian Health Research Institute**, the Center for Discovery and Innovation, **the Bear's Den**, the next generation of physicians at Hackensack Meridian School of Medicine, and the mindset and mentality of those who care in our medical centers and hospitals every day.



Powell-Elliott Panelist at Annual Spring Symposium

Sandra Powell-Elliott, MBA, the chief innovation and commercialization officer for the network, brought her expertise as part of a panel at the Rutgers University Edward J. Bloustein School of Planning and Public Policy Annual Spring Symposium and Healthcare Workshop.

"Life Sciences and Healthcare Institutions: Partners for Life," was held on Cook Campus on April 26, 2023, and Powell-Elliott was part of the first panel concerning conducting and funding research.

She was joined on the hour-long panel by researchers and medical doctors from Rutgers, Virtua Health and elsewhere.



Kountz Thanked by ACGME for Service

David Kountz, M.D., was recently given a nice "thank you" by the Accreditation Council for Graduate Medical Education (ACGME).

Dr. Kountz, the school's senior associate dean of Diversity, Equity and Inclusion, was cited by Thomas J. Nasca, M.D., MACP, the president and CEO of the ACGME, for his many hours dedicated as a volunteer for a review committee, in a letter addressed to Ihor Sawczuk, M.D., FACS, president of Academics, Research and Innovation for HMH.

"I want to personally express my sincere thanks to you for your continued support of Dr. Kountz's commitment to the physicians of tomorrow, the future of medical education and the health of the public," wrote Nasca.

Dr. Kountz is also the chief academic officer and vice president of Academic Affairs for Hackensack Meridian Health.



Fitzgerald Named President of Mid-Atlantic Biological Safety Association

Sean Fitzgerald, MPH, RBP, manager of Biological Safety and Environmental Health and Safety, has been officially elected President of the Mid-Atlantic Biological Safety Association.

Fitzgerald, who is also the chair of the Institutional Biological Safety Committee and chair of the Institutional Animal Care and Use Committee at Hackensack Meridian Health, was elected in June 2023.

The honor encompasses the Tri-State area all the way down to Atlanta, with representation from many major institutions throughout the region.

"It should be a great opportunity to continue to put HMH and the CDI on the map in even more aspects of research excellence," said Fitzgerald.

Top Grants from Last Quarter

#	PI Name	Division	Service Line	Sponsor	Award Number	Grant Title	Date Awarded / Signed Agreement	Proposed Period of Performance	Human Subjects Yes / No	Cancer Relevance	Direct Cost	Indirect Cost	Total Budget
1	Perlin, David	CDI	Infectious Disease	NIH - NIAID	5U19AI142731-05	Center to Develop Innovative Therapeutics to Multidrug Resistant High-Threat Bacterial Agents	4/21/2023	05/01/2023-04/30/2024	No	No	\$5,198,920	\$1,322,405	\$6,521,325
2	Shah, Aakash	JSUMC	Community	DOJ OJP	15PBJA-22-GG-04737-CVIP	Project Heal: Expansion of Community-Based Violence Intervention & Prevention	4/6/2023	10/01/2022-09/30/2025	No	No	\$1,866,002	\$133,401	\$1,999,403
3	Gengenbacher, Martin	CDI	Infectious Disease	NIH - NIAID	5R01AI161013-03	Initiatives at Jersey Shore University Medical Center	6/22/2023	07/01/2023-06/30/2024	No	No	\$890,199	\$386,304	\$1,276,503
4	Mu, Liancai	CDI	Parkinson's Disease	DOD	HT94252310481	Harnessing B Cells for TB Vaccine Development to Improve Therapy of TB and TB-HIV Coinfection	6/16/2023	07/01/2023-06/30/2026	Yes	No	\$677,583	\$522,417	\$1,200,000
5	Shah, Aakash	JSUMC	Community	DOJ OAG	ARHV-05-21	FY21 ARP Hospital Based Violence Intervention Program	6/2/2023	01/01/2023-12/31/2023	No	No	\$1,028,850	\$-	\$1,028,850



RESEARCH UPDATES & EVENTS

SUMMER 2023

Save These Dates in Your Calendars

You won't want to miss our research events this fall! We are planning an array of topics, including export controls and research, research data platforms and more biostatistics presentations. There will also be discussions on whether research with animals is really necessary, how AI impacts research and more.

Please check out our fall offerings [here](#). More information will be sent out via eResearch as we get closer to the dates; however, you may want to block off your calendars in advance for topics that especially interest you.

If you have any research-related topics that you would like us to include in our educational programming, please click [here](#) to submit a request.

eResearch Gets an Upgrade

The electronic IRB protocol submission that the HMM research community recognizes as "eResearch" is undergoing a major upgrade. eResearch will now be HMM's one-stop-shop for electronic research administration systems starting with the Conflicts of Interest (COI) module going live in August 2023, and the Grants and Agreements module coming soon in 2024. If you have questions on access, modules, upgrades or reviews, please direct them to the following:

COI Module - COI@hmn.org

IRB Protocol Submission - hmhirb@hmn.org

Ancillary Reviews - contact the reviewer directly

Complete your COI Disclosure for Research in eResearch

The Conflicts of Interest (COI) module goes live in August 2023. All COI disclosures will be submitted within eResearch by navigating to the COI Module tab. Some key highlights are:

- Integration with other research modules (IRB and future Grants/Agreements)
- Integration with COI CITI training modules
- Historical disclosure information (2023 and future) are retained
- Access is through your HMM credentials (no additional passwords to remember)
- Automatic re-file reminders and notifications sent by the system
- Easily update your disclosure any time by logging in and add/removing interests

- Single disclosure for all HMM disclosure requirements (no more filing multiple HMM disclosures throughout the year for those that are required to file more than one)

Here is what to expect with the new module:

- The REDCAP interim form is no longer collecting disclosures.
- If you have an up-to-date disclosure (filed in the last 12 months) and have no interests disclosed - completion dates are being imported and no action is required right now, unless you have a new interest and need to update your form.
- If you have an up-to-date disclosure with interest(s) disclosed - your disclosure information is being imported into your profile and you will be required to login and verify the information is correct. Individuals that meet this criteria will be contacted directly by COI@hmn.org with step-by-step instructions and additional training will be offered.
- If you or a study team member has an out-of-date disclosure (not filed in last 12 months)
- A notification will be sent by the system that a disclosure profile needs to be updated. You need to login and update ASAP to prevent study pauses/delays.
- If you have an active COI management plan - All active management plans will be imported into the system. Individuals will require a one-time re-acknowledgement of the management plan. Individuals will be contacted directly by COI@hmn.org with step-by-step instructions and additional training will be offered.
- Individuals required to complete HMM's annual network disclosure (non-research) will be asked to re-certify their disclosure during the 2023 network reporting period. More information will be distributed to those that meet this HMM requirement.
- Stay tuned to eResearch announcements for training and information sessions.

Additional training is available to individuals and departments upon request by contacting COI@hmn.org.

Step-by-step instructions for updating a disclosure profile can be found [here](#).

Research Compliance Website Now Available

Research compliance now has a website. HMM researchers can easily access policies, information, and resources for ensuring compliance. Topics include:

- Clinical Research Billing Compliance
- Conflicts of Interest and Research
- Data Management and Sharing
- Export Controls
- Foreign Interactions and Research Security
- Privacy and Cyber Security Considerations for Research
- Responsible Conduct of Research
- Research Misconduct
- Research Monitoring and Audit Program

<https://www.hackensackmeridianhealth.org/en/research/research-compliance>

Required Order of Submissions to OnCore, eResearch, and Other Research-Related Systems

Consistency among research-related systems is critical, so the order that studies are submitted to or revised within the different systems also becomes very important. When a new study or a modification is ready to be initiated, eResearch must be the first system within which the study or modification is entered. When the study is submitted within eResearch and a Pro# assigned, a shell may be created within OnCore if relevant (i.e. clinical trials). Please note that we are working on an initiative to automate this shell creation in the future. If the study will rely on an external IRB, the Research Integrity Office will release an institutional clearance letter within eResearch once all institutional reviews have been completed, which will allow submission to the external IRB.

Personnel and other study modifications utilize this same review order. For example, when an investigator is being added to the study, the modification must first be made within eResearch. Reviews will be completed by COI, Research Credentialing and any other relevant review area, and the modification will result in an update finalization letter within eResearch. Only after this is received can a submission be made to the external IRB of record for their review of the change(s). After the IRB of record has approved the change(s), OnCore may be updated as well.

Updating OnCore or the IRB of record before eResearch is updated and institutional approvals are provided will result in a finding of noncompliance and the appropriate institutional actions will be taken.

Please contact the Office of Research Administration at ORA@hmn.org with questions.

Please review the [HRPP SOPs](#) for additional information on expectations, procedures and regulatory requirements for those engaging in Human Subjects Research.

Documentation of Re-Consenting Subjects

A recurring observation made by Research Compliance during routine research audits has been incomplete documentation for re-consenting of subjects on clinical trials when an IRB makes a request that subjects be re-consented. This type of request is typically due to a change in the risk profile of the study drug.

A patient consent form is a legal document; therefore it is essential to document in the study and record the details regarding why the re-consent took place. An example of such language could include a brief statement such as: "The subject was re-consented at this time due to the risk of mild liver toxicity being added to the possible side effects of the drug X." This additional statement provides transparency and legal assurance that the essential elements of the consent changes were conveyed and the subject continues to willingly participate in the research.

Questions regarding best practices for study documentation can be directed to martin.kleber@hmn.org and additional resources can be found on the [Research Monitoring and Audit Website](#).



FEATURED RESEARCHER

SUMMER 2023



The CDI Experts: Makohon-Moore Dissects Cancer's Evolution

The bioreactor in the Makohon-Moore Lab looks, to a layman, like something out of an old science-fiction movie. The tubes and containers have minutely different environments – complete nutrition, deprivation, or starvation – to show how certain cancer cell lines within react and grow, survive or die, based on their surroundings. The fluids and material flow in and out, like it is in and of itself a living thing.

To a scientist like Alvin Makohon-Moore, this is the closest science has yet come to growing cancer in a controlled environment – mimicking its natural progression as closely as possible, in order to understand its dynamics ... and how we may yet conquer it someday.

Makohon-Moore, assistant member of the Hackensack Meridian Center for Discovery and Innovation (CDI), arrived last year and has since been pushing forward the study of cancer's evolution – how it arises, changes, grows, spreads, and ultimately, kills.

What has been dubbed “the emperor of all maladies” has been with humanity since we arose as a species – and Makohon-Moore reflects that scientists are still playing catch-up. To him, his bioreactor is going to shed some light in untangling cancer's evolution, as entangled and entwined as it is with our shared history.

“This takes the evolutionary process and shows its dynamics in real time,” said Makohon-Moore recently in his laboratory.

Makohon-Moore is assessing the evolutionary foundations of cancer and producing results which complement so much of the CDI's groundbreaking research in cancer. The work could help us better understand the timing and weaknesses of cancers, thereby pointing the way toward treatments in the years to come.

“Alvin is looking into the fundamentals of cancer evolution – which has the potential to better understand ways to change a cell's cancer potential,” said David Perlin, PhD, the chief scientific officer and executive vice president of the CDI. “It complements so much of the other innovative cancer research going on at the CDI and at HMH; his findings are certain to advance the science of cancer significantly.”

[READ MORE](#)



FEATURED RESEARCHER

SUMMER 2023

Fortunato Battaglia, M.D., Ph.D.

Professor

Department of Medical Sciences and Department of Neurology
Director, Neuroscience and Behavior Course
Hackensack Meridian School of Medicine

Overseeing student research can be involved. It requires consistent guidance on all aspects of the project, from the research idea to the execution of the study and finally, the publication. Mentors need to impart to their students the importance of a comprehensive literature review, a feasible idea, careful attention to the protocol, and finally an unbiased and honest perspective in the poster or manuscript. For that reason, many mentors consciously decide to start off very small with their students - a simple retrospective chart review with limited data or a basic survey.

Fortunato Battaglia, M.D., Ph.D., professor of medical sciences at the Hackensack Meridian School of Medicine, is not like many mentors.

Rather, he strives to stretch his students to conduct research that is challenging, unique, and, at times, completely “out of the box.” While this would entail quite a bit of extra work for any mentor, Dr. Battaglia refuses to be deterred from a promising study simply because it requires a greater investment. For him, it is worth his while, as he ranks mentorship among his most gratifying accomplishments.

Dr. Battaglia met with us to share more about his role as a mentor, his research and the driving theories behind much of his work.

How did you become interested in medicine, and specifically neurology?

There were many doctors in my family, and it was always expected that I would follow in their footsteps. I knew I wanted to be a doctor since I was a little kid; I hadn't really considered any alternatives. However, I hadn't always been interested in neurology. In medical school, I was originally interested in ophthalmology. But studying the neurophysiology of perception ended up sparking my interest in neurology and the study of the brain as a whole, not just the part associated with vision.

Neuropsychiatry seems really exciting because advances in technology have enabled us to be able to observe activity in the brain from so many different perspectives - temporally and structurally. However, there seems to be less momentum than in other areas; there are still no cures for schizophrenia, Alzheimer's disease, and many other conditions associated with the brain.

What is your perspective?

It is true that many conditions remain without definitive cures and that headway has been limited in certain areas. For example, while new antidepressants and antipsychotics have been brought to market over the last few decades, they're not much more effective than what we could offer years ago. However, we are still making great progress in terms of other treatments. In fact, it is a very exciting time for my main field of research, non-invasive brain stimulation. I have been interested in this therapy since medical school and have maintained this interest throughout my training and as a scientist myself. Essentially, non-invasive brain stimulation is as it sounds: stimulating the brain in a manner that does not involve pain or anesthesia. This is a popular and relatively new way to treat depression, migraines, Alzheimer's disease, obsessive-compulsive disorder, and much more. These techniques, which are now FDA-approved and used clinically in many hospitals, enable us to offer patients the best of both worlds: the effectiveness of brain stimulation without the problematic side effects of the more invasive methods. While that is a great tool, it is just one of many that should be utilized. I am a proponent of integrative psychiatry, which involves treating psychiatric disorders with a combination of pharmacotherapy, psychotherapy and other approaches. Essentially, it involves employing various strategies to address a concern, rather than focusing on just one.

FEATURED RESEARCHER:

Fortunato Battaglia, M.D., Ph.D. (cont'd)

Your publications involve studies addressing various disorders rather than a narrow focus on one condition. What would you consider to be the driving goal or unifying theme behind your work?

I have two main focuses: first, the concept of brain stimulation that I mentioned earlier. I believe that it can be very instrumental in addressing a whole host of conditions. Secondly, I study neuroplasticity - or synaptic plasticity - because I believe that abnormalities in this phenomenon may be the underlying cause of pathophysiology in neuropsychiatric conditions. Synaptic plasticity refers to changes in the brain's synapses, the little meeting grounds where neurons can communicate with each other. There can be a strengthening of synapses between neurons, such as long term potentiation, which, for example, may lead to increased memory, or a weakening of synapses, which can have the opposite effect. Plasticity-based interventions can be applied to several diseases because they act to normalize and restore synaptic plasticity, which is a neurocorrelate for learning and memory and bases for normal behavior. That is why I have written about many different disorders, because this approach can be used for a fairly large scope of populations.

Can you share some of the projects that you are working on that are especially exciting for you nowadays?

Fortunately, I have been involved in many exciting initiatives lately, made all the more exciting and fun with student involvement. I'm researching a wide breadth of topics with different students. For example, some students are working with me on animal models and brain stimulation. We are studying patients with depression and drug addiction, and we are working on designing a clinical study addressing comorbid depression with substance use disorder. We are looking into whether we can improve mood and thereby reduce cravings. I am working with another group of students to study mental health in medical students. Specifically, we are looking at the relationship between stress in medical school and risky behavior in students, including cannabis and stimulant use.

Another theme in my research has been an international one. It has been fantastic for the students because they get to interact with other students from different countries. For example, one of our international studies was to assess the effects of COVID-19 infection on medical students during the omicron pandemic. China implemented some extreme measures during that time and we wanted to explore the burden placed on students. This ended up being trickier than anticipated because we had created our tools in Google, which we later learned is banned in China. So, we needed to figure out how to convert the tools onto a Chinese program.

Another example of our international research was born from my students' and my interest in public health and involved a

collaboration with students in Italy. We conducted a study on the mental health of African refugees that arrived in Italy. Essentially, we were interested in the development of psychiatric conditions in that group, along with potential disabilities associated with those conditions. We collected data from 90 patients in a psychiatric treatment center in Italy, where the refugees underwent assessments. This ended up being a major undertaking because the participants spoke 23 different African dialects that all needed to be translated!

You earned an M.D. and a Ph.D. What drove you to get the Ph.D.? How did you know that you wanted to engage in research?

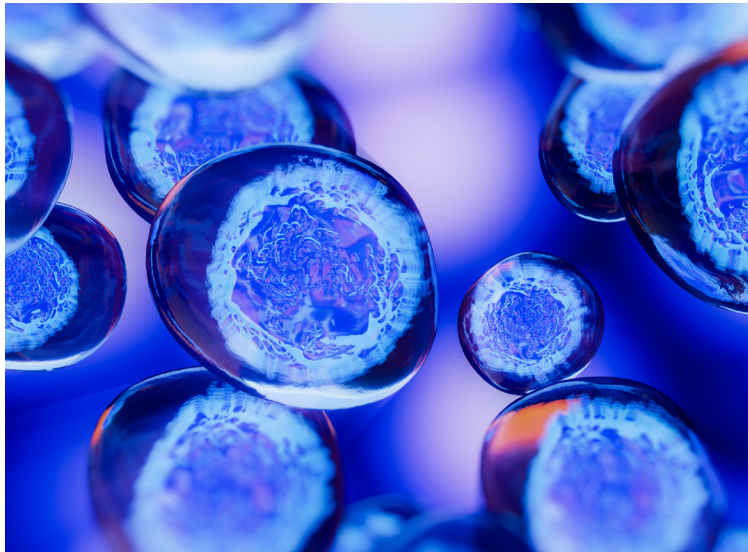
Research has been a passion of mine since my first year of medical school. I became involved in research very early. In Europe, physicians are given the opportunity to spend one year of residency in a host country doing research. I took advantage of that option, and during my third year of neurology residency, I started a clinical fellowship at the NIH. There, I was witness to the development of some technologies that had the potential to be very useful to neurology patients. I earned my Ph.D. and later came to the U.S. and did post-doc work at NYU and Columbia. During my Ph.D., I focused more on the cognitive psychology aspect of neuroscience and refined my interest in synaptic plasticity. I was able to look at the topic from different angles: first clinically, then in an animal model, then via biomarkers, and finally toward therapeutic applications.

What are your thoughts on medical students becoming involved in research? Is it important for them to become involved at that stage or can they defer research until later in their careers?

I would strongly advise students to become involved in research. It is so critical to the medical education process at this point, that it is practically mandatory. Because of changes in the USMLE step 1, which is just a pass/fail test now, publication has become a crucial way to distinguish yourself and gain entry to a competitive research program. Some of the most competitive residency programs have applicants with 4-5 publications. So, my advice is to approach a researcher whose work interests you and see if you can become involved. I have many students approach me regularly, and it is so much fun working with them. In fact, I collaborate with former students who went on to become accomplished scientists; we are now colleagues.

What are some of your hobbies and interests outside of work?

I really enjoy movies and music. I also love living in New York City and the culture and activities that the city affords. I enjoy traveling, as well. While I have been on a bit of a hiatus since COVID, I want to start again soon. Among my favorite impetuses for traveling are work conferences. It is great to meet up with old friends who I trained with in the past. I don't participate in many sports nowadays, but I was once a fairly dedicated tennis player, and I still follow the tournaments.



FEATURED RESEARCH ADMINISTRATOR

SUMMER 2023



Barbara S. Reich, MLS, AHIP

Director, Medical Library,
Hackensack University
Medical Center

After three decades in the field, Barbara Reich knows that she is unlikely to learn of the clinical outcomes associated with most of the literature searches that she conducts for clinicians. Most of the time, the clinician will request assistance with a literature search on a particular topic and will go on his or her way after

it's been completed. But over the course of Barbara's career, there have been times when they have returned to share what came of her help - and it brings her work, and its impact, full-circle.

There was the time that the information gleaned in one of her searches led to a baby's life being saved. Her work has also led to treatment plan modifications, policy changes, critical equipment purchases, and educational initiative implementations. Barbara views herself as a member of the team of healthcare professionals, striving for the best patient care possible.

As further evidence of her collaborative spirit, she met with us to share more about the library's services, how researchers can benefit from them and what drew her to her chosen career path.

What role do you (and other members of the library) play in assisting researchers with their studies?

My role is to make sure that people get the information they need, in one way or another. The HMH librarians assist researchers with literature searches and teach them how to conduct them on their own. They also show researchers what resources the library has and which ones to use when. Subscriptions are also an important piece of the library's services. While accessing full text articles may seem pretty seamless on the HMH network, it would actually not be possible without the library's subscriptions to a multitude

of scientific journals. We also offer interlibrary loan services and document delivery for those researchers that need access to articles which are not available via our subscriptions.

How did you become interested in becoming a medical librarian?

As a kid, I was always very interested in medicine. People encouraged me to go to medical school and become a physician throughout my childhood and adolescence, but I preferred the academic angle rather than working as a clinician. At the time, I toyed with the idea of getting an advanced degree in the sciences, but it did not seem viable right then. I embarked on a completely different career for a few years. Then, at the age of 30, I met someone who was doing a project with a pharmaceutical company's library. It was only then that I realized that there are subject-specific libraries. It occurred to me that I could actually make a career out of medical information, so I went to school specifically to become a hospital librarian. This is unusual, since most people go to school to become librarians and then end up as hospital librarians. In my case, that was my intention from the beginning.

In addition to your role as a medical librarian, you are also an Institutional Review Board (IRB) member. What led you to join the Board?

I became interested in the IRB 20 years ago. A close family member had been admitted to the Emergency Room (at a non-HMH hospital). When I got there, I started asking questions about her status and looking at her medical record. I noticed something about her being enrolled in a clinical trial. My relative, the patient, knew nothing about it, so I asked the resident on duty. He assured me that she had given informed consent, but that seemed unlikely since she was legally blind and was hard of hearing (in a noisy setting). That was my first personal interest in protecting human subjects. I also encountered a really impactful news story about [a healthy patient at Johns Hopkins who had died after participating in a clinical trial](#). The researcher had claimed that he did a literature search that indicated that the drug had no ill effects, and the IRB had taken his word for it. Within hours of the incident, medical librarians found that adverse events had been recorded. Had a proper literature search been conducted, this information would have been found and the study would likely have never taken place. (Cont'd)

FEATURED RESEARCH ADMINISTRATOR:

Barbara S. Reich, MLS, AHIP (*cont'd*)

Based on your experience as a medical librarian and IRB member, what are your suggestions for new or inexperienced researchers for the best outcomes in their research?

On a general level, if you are considering participating as a principal investigator on a sponsored study, make sure you know what you're getting into. It's important to have a good sense of the study and scientific background. Read the protocol and make sure you understand it. Look at the references and ensure they're from legitimate sources, that the references say what they're explaining. Sometimes people will only read the abstract, and it is not always congruous with what the article supports.

If you are considering embarking on a homegrown protocol, start early with a good literature search. Make sure you have a well-thought-out question to search. The research question might differ a bit from your search questions; the former may be a specific question, while the latter might encompass 3-4 related questions.

From the perspective of a medical librarian: Make sure that you reach out to the librarians for guidance, even if you would like to do your own searches. It is more complicated to do a really good search than people realize. It is relatively easy to do a mediocre search, and unfortunately, it is not always transparent that the search was not properly performed. There have been countless times where physicians have finished searches that have produced a handful of articles - only to be provided with hundreds more when the search was performed by a librarian. Another tip for those wanting to do their own searches: pick an interface and learn to use it well. It is better to be really really good at one interface (for example, accessing MEDLINE through PubMed alone) than to try to know how to search every interface that exists.

From the perspective of an IRB reviewer: Pay careful attention to detail in your application. Lack of attention to detail makes reviewers nervous and prompts us to read everything more carefully. It is especially concerning when we see conflicting information in different parts of the application. It makes us wonder if the researcher really even knows what's in the protocol. Essentially, we want to see that the study has a strong scientific foundation and that the execution is carefully planned. Every trial puts patients in some amount of risk, however small in some cases, and we don't want to do that unless there is going to be a concomitant benefit to society.

Beware of therapeutic misconception in both your application and in addressing patients. I've seen this as a reviewer, but also as a friend of a patient. A close friend of mine was enrolled in multiple clinical trials for a certain condition. Fortunately, over time, he began to rally and do better. When he returned to the office, the physician and nurse casually mentioned that given his improvement, they suspected that he must have been assigned to the test article rather than the control for one of the trials. It is critical for researchers to remember that however promising the

study may be, they don't yet know the answers. That is the reason for doing the research.

Finally, make sure you work out the consenting logistics very thoroughly. During the consenting processes for the different clinical trials in which my friend participated, I became aware of some variability in comprehensiveness and in execution. The consent process needs to conform to exactly what was approved by the IRB.

How should a potential researcher get started working with the library?

Reach out to us in whatever way is best for you: email us, call us or just show up. We are here to help you and are always happy when people express interest in the services we offer. [Here](#) are some instructions for accessing our resources online.

What are some of your favorite pastimes when you are not in the library?

I have a few interrelated hobbies: camping, hiking, kayaking, live music and cooking. I have been passionate about live music for a long time and generally see at least 50 live shows a year. I enjoy many different types of music, including Jam Band, Americana, folk and world music. I started camping because I wanted to go to a music festival that was too far to drive, and there were no hotels. I grew up in the city and thought I would hate it, but I discovered that there's nothing I liked better than a campfire, waking up in a tent, cooking breakfast outside for all my friends and seeing my favorite bands. I was actually introduced to my husband at a music festival.



HMSOM RESEARCH BULLETIN

SUMMER 2023

HMSOM Student Publishes Correspondence in *The Lancet*

A second-year Hackensack Meridian School of Medicine student has published a piece of correspondence in *The Lancet*, which questions some recent research about injectables for treatment of schizophrenia.

Maxwell Price co-authored the piece, titled [“The use of long-acting injectables in early-phase schizophrenia.”](#) in this month’s issue of the esteemed medical journal. His father, psychiatrist Richard L. Price of Weill Cornell Medical College, is the other author.

The correspondence questions some recently published studies, according to the younger Price.

“Our *Lancet* article was inspired after reading a large research study conducted throughout Europe and Israel that appeared to be methodologically problematic leading to an erroneous conclusion,” he said. “I analyzed their study carefully, including all the details of their supplemental information, and found an alternative conclusion that more closely comports with our own clinical experience and better explains their data.”



Price finished his undergraduate degree in neuroscience at Columbia University last year, at age 19, before starting his stint at HMSOM. He plans to finish his classroom and clinical M.D. requirements over three years, and then earn an MPH, concentrating in biostatistics, in his fourth year.

Price said it was his mentors, his father and beyond, who have given him inspiration early in his career.

“I am appreciative of Psychiatry Chair, Dr. Gary Small for his ongoing career advice, and (CDI scientist and professor) Dr. Benjamin Tycko for his research mentorship,” said Price.





QUARTERLY QUESTION

SUMMER 2023

What is the minimum number of Institutional Review Board members required by federal regulations?

To answer the question, please click [here](#).

The first person to submit the correct answer will receive a Hackensack Meridian *Health* gift.